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For: *SPECIFICATION OF DIAGNOSTICS AND THERAPY OF EPSTEIN-BARR VIRUS
IN AUTOIMMUNE DISORDERS*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants cite the following publications, which are listed in the enclosed 21 pages of Form PTO-1449. Enclosed are copies of the International Search Reports for International Application Number PCT/US/91/00682 corresponding to U.S.S.N. 07/648,205 and PCT/US93/03484 corresponding to U.S.S.N. 07/867,819.

This application is a Continuation-In-Part of U.S.S.N. 07/160,604, filed on November 30, 1993, which is a Continuation-In-Part of 07/867,819, filed on April 13, 1992 which is a Continuation-In-Part of 07/648,205, which is a Continuation-In-Part of 07/472,947 now abandoned.

It is believed that no fee is required with this submission. However, if an additional fee is required, the Assistant Commissioner is authorized to charge Deposit Account No. 01-2507.

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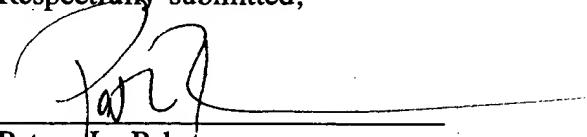
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their

claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst

Reg. No. 31,284

Dated: February 2, 1998

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Applicant: John B. Harley et al.

Serial & Docket No.: 08/781,296

OMRF 161

Filed: January 13, 1997

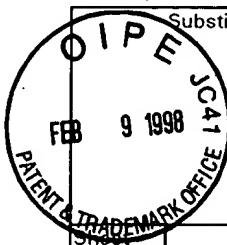
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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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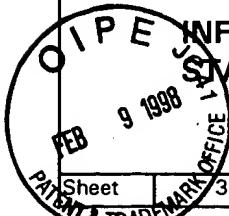
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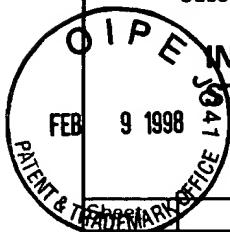
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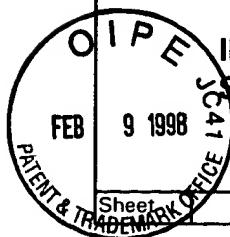
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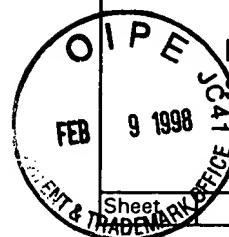
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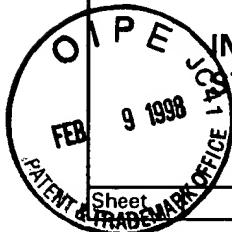
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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned

Attorney Docket Number

OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		Fox, et al., "Detection of Epstein-Barr Virus-Associated Antigens and DNA in Salivary Gland Biopsies from Patients with Sjogren's Syndrome", <u>J. Immunol.</u> , 137:3162-3168 (1986)	
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Application Number	08/781,296
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First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
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		Guldner, et al., <u>The Journal of Immunology</u> , 141(2):469-475 (July 15, 1988)	
		Gutierrez, et al., "Switching Viral Latency to Viral Lysis: A Novel Therapeutic Approach for Epstein-Barr Virus-Associated Neoplasia", <u>Cancer Res.</u> , 56:969-972 (1996)	
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		Herbert, et al., <u>Dictionary of Immunology</u> 3 rd Ed. Blackwell Scientific Publications Oxford UK page 14 91985)	
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		Hinterberger, "Isolation of Small Nuclear Ribonucleoproteins Containing U1, U2, U4, U5, and U6 RNAs", <u>Biol. Chem.</u> , 258:2604-2618 (1983)	
		Hollinger, et al., "Seroepidemiologic Studies in Systemic Lupus Erythematosus", <u>Bact. Proc.</u> , 131:174 (1970)	
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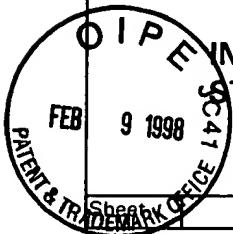
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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

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		James & Harley, "Linear Epitope Mapping of an Sm B/B' Polypeptide", <u>J. Immunol.</u> , 148:2074-2079 (1992)	
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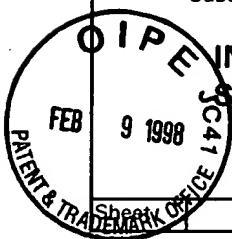
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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

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		Kitagawa, et al., <u>Immunol. Lett.</u> , 17:249-252 (1988)	
		Klippel, et al., "Epstein-Barr Virus Antibody and Lymphocyte Tubuloreticular Structures in Systemic Lupus Erythematosus", <u>Lancet</u> , 2:1057-1058 (1973)	
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		Lehman, et al., "Spreading of T-Cell Autoimmunity to Cryptic Determinants of an Autoantigen", <u>Nature</u> 356:155-157 (1992)	
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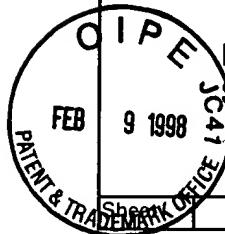
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First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
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		Leif, "Maverick Herpes Receptor Sparks Search for KS Drug", <u>Bio World Today</u> , 8(17):1 (1997)	
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		Mendlovic, S., et al., "The Genetic Regulation of the Induction of Experimental SLE," <u>Immunology</u> 69:228-236 (1990)	
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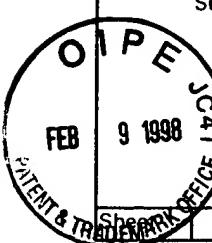
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		Mendlovic, S., et al., "Induction of an SLE-Like Disease in Mice by a Common Anti-DNA Idiotype," <u>Proc. Natl. Acad. Sci. USA</u> 85:2260-2264 (1988)	
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		Miller, Epstein-Barr virus. pp. 1921-1958;	
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		Morgan, <u>Vaccine</u> , 10:563-571 (1992)	
		Morgan, et al., <u>J. Med. Virol.</u> , 29:74-78 (1989)	
		Morland, et al., "Anti-idiotype and Immunosuppressant Treatment of Murine Lupus", <u>Clin. Exp. Immunol.</u> , 83(1):126-132 (1991)	
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		Mosier, et al., <u>Nature</u> 335:256-259 (1988)	
		Munves, et al., "Antibodies to Sm and RNP," <u>Arthritis Rheum.</u> , 26: 848-853 (1983)	
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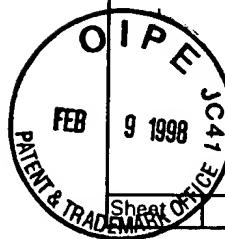
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Sheet 14 of 21

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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

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		Newkirk, et al., "Detection of Cytomegalovirus, Epstein-Barr Virus and Herpes Virus-6 in Patients with Rheumatoid Arthritis With or Without Sjogren's Syndrome", <u>Br. J. Rheum.</u> , 33:317-322 (1994)	
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		Petterson, et al., "The Structure of Mammalian Small Nuclear Ribonucleoproteins", <u>J. Biol. Chem.</u> , 259:5907-5914 (1984)	
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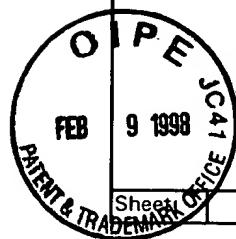
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		Ravirajan & Staines, "Involvement in Lupus Disease of Idiotypes Id.F-423 and Id.IV-228 Defined, Respectively, Upon Foetal and Adult MRL/Mp-lpr/lpr DNA-binding Monoclonal Autoantibodies" <u>Immunology</u> , 74:342-347 (1991)
		Reichlin, et al., "Autoantibodies to the URNP Particles: Relationship to Clinical Diagnosis and Nephritis," <u>Clin. Exp. Immunol.</u> 83:286-290 (1991)
		Reichlin, et al., "Concentration of Autoantibodies to native 60-kd Ro/SS-A and Denatured 52-kd Ro/SS-A in Eluates from the Heart of a Child Who Died with Congenital Complete Heart Block," <u>Arth. And Rheum.</u> 37:1698-1703 (1994)
		Renz, M., et al., "Expression of the Major Human Ribonucleoprotein (RNP) Autoantigens in <i>Escherichia coli</i> and their Use in an EIA for Screening Sera from Patients with Autoimmune Diseases," <u>Clin. Chem.</u> 35:1861-1863 (1989)
		Reuter, et al., <u>PNAS</u> 83:8689-8693 (1986)
		Rhodes, et al., "Autoantibodies in Infectious Mononucleosis Have Specificity for the Glycine-Alanine Repeating Region of the Epstein-Barr Virus Nuclear Antigen", <u>J. Exp. Med.</u> , 165:1026-1040 (1987)
		Rokeach, et al., "Molecular Cloning of a cDNA Encoding the Human Sm-D Autoantigen," <u>Proc. Natl. Acad. Sci. USA</u> 85:4832-36 (1988)
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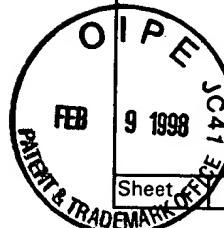
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		Sabbatini, et al., "Autoantibodies from Patients with Systemic Lupus Erythematosus Bind a Shared Sequence of AmD and Epstein-Barr Virus-Encoded Nuclear Antigen EBNA I", <u>Eur. J. Immunol.</u> , 23:1146-1152 (1993)	
		Saito, et al., "Detection of Epstein-Barr Virus DNA by Polymerase Chain Reaction in Blood and Tissue Biopsies from Patients with	
		Sasaki, et al., "In Vitro Manipulation of Human Anti-DNA Antibody Production by Anti-idiotypic Antibodies Conjugated with Neocarzinostatin", <u>The Journal of Immunology</u> , 142(4):1159-1165 (1989)	
		Schaack, "Molecular Mimicry in HLA-B-27-Related Arthritis," <u>Annals of Internal Medicine</u> , 111(7):581-591 (October 1, 1989)	
		Schmauss, et al., "A Comparison of snRNP-Associated Sm-Autoantigens: Human N, Rat N and Human B/B (abstract)", <u>Nuc. Acid Res.</u> , 17:1733-43 (1989)	
		Schoenfeld, et al, "Modulation of Experimental SLE Induced in Naive Mice by a Pathogenic Anti-DNA Idiotype (16/6 Id)," <u>Proceedings of the Second International Conference on Systemic Lupus Erythematosus</u> Tokyo, Japan Professional Postgraduate Services 83 (1989)	
		Schoenfeld, et al, "Pathogenic Idiotypes of Autoantibodies in Autoimmunity: Lessons from New Experimental Models of SLE," <u>FASEB J.</u> 4:2646-2651 (1990)	
		Scofield, et al., "60kD Ro/SSA Autoepitopes are Found in Regions of Homology Between Ro/SSA and the Nucleocapsid Protein of Vesicular Stomatitis Virus," <u>Arthritis and Rheumatism</u> , 33(9):S101 (1990)	
		Scofield, et al., "Autoantigenicity of Ro/SSA Antigen is Related to a Nucleocapsid Protein of Vesicular Stomatitis Virus", <u>Proc. Natl. Acad. Sci. USA</u> , 88:3343-3347 (1991)	
		Scofield, R., "A Common Autoepitope Near the carboxyl Terminus of the 60-kD Ro Ribonucleoprotein: Sequence Similarity with a Viral Protein," <u>Journal of Clinical Immunology</u> 11(6):378-388 (1991)	
		Scofield, et al., "The Autoantigenicity of Human 60kD Ro/SSA is Related to Hormologies Between Ro/SSA and the Nucleocapsid Protein of Vesicular Stomatitis Virus," <u>Clinical Research</u> , 38(2):316A, (1990)	
		Scofield, et al., "Development of the Anti-Ro Autoantibody Response in a Patient with Systemic Lupus Erythematosus", <u>Arthritis & Rheumatism</u> , 39(10):1664-1688 (1996)	

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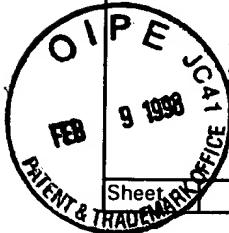
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		Scofield, et al., "Immunization with Short Peptides from the Sequence of the Systemic Lupus Erythematosus-Associated 60-kDa Ro Autoantigen Results in Anti-Ro Ribonucleoprotein Autoimmunity", <u>J. Immunology</u> , 4059-4066 (1996)	
		Scofield, "Autoimmune Thyroid Disease in Systemic Lupus Erythematosus and Sjogren's Syndrome", <u>Clin. Exp. Rheum.</u> , 14:321-330 (1996)	
		Scofield, "HLA-B27 Binding of Peptide From Its Own Sequence and Similar Peptides From Bacteria: Implications For Spondyloarthropathies", <u>Lancet</u> , 345:1542-1544 (1995)	
		Sculley, et al., "Reactions of Sera from Patients with Rheumatoid Arthritis, Systemic Lupus Erythematosus and Infectious Mononucleosis to Epstein-Barr Virus-Induced Polypeptides", <u>J. Gen. Virol.</u> , 67:2253-2258 (1986)	
		Sharpe, et al., "Isolation of cDNA Clones Encoding the Human Sm B/B' Auto-Immune Antigen and Specifically Reacting with Human Anti-Sm Auto-", <u>FEBS Lett.</u> , 250:585-590 (1989)	
		Sillikens, et al., "Human U1 snRNP-specific C Protein: Complete cDNA and Protein Sequence and Identification of a Multigene Family in Mammals", <u>Nucleic Acids Res.</u> , 16:8307-21 (1988)	
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		Sumaya, et al., "Increased Prevalence and Titer of Epstein-Barr Virus Antibodies in Patients with Multiple Sclerosis", <u>Ann. Neurol.</u> , 17:371-377 (1985)	

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		Suzuki, et al., "Viral Interleukin 10 (IL-10), the Human Herpes Virus 4 Cellular IL-10 Homologue, Induces Local Anergy to Allogeneic and Syngeneic Tumors", <u>J. Exp. Med.</u> , 182:477-486 (1995)	
		Takeda, Y., et al., "Antigenic Domains on the U1 Small Nuclear Ribonucleoprotein-associated 70kD Polypeptide; a comparison of regions selectively recognized by Human and Mouse Autoantibodies and by Monoclonal Antibodies," <u>Chem. Abstracts</u> 116(1): ab. No. 4803a (January 6, 1992)	
		Tan, et al., "The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus", <u>Arthritis Rheum.</u> , 25:1271-1277 (1982)	
		Tan, et al., "Characteristics of a Soluble Nuclear Antigen Precipitating with Sera of Patients with Systemic Lupus Erythematosus," <u>J. Immunol.</u> , 96:464-471 (1966)	
		Tateishi, et al., "Spontaneous Production of Epstein-Barr Virus by B Lymphoblastoid Cell Lines Obtained from Patients with Sjogren's Syndrome", <u>Arthritis Rhuem.</u> , 36:827-835 (1993)	
		Theissen, et al., "Cloning of the Human cDNA for the U1 RNA-associated 70K Protein," <u>EMBO J.</u> , 5:3209-17 (1986)	
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		Tsai, et al., "Detection of Epstein-Barr Virus and Cytomegalovirus Genome in White Blood Cells from Patients with Juvenile Rheumatoid Arthritis and Childhood Systemic Lupus Erythematosus", <u>Int. Arch. Allergy Immunol.</u> , 106:235-240 (1995)	
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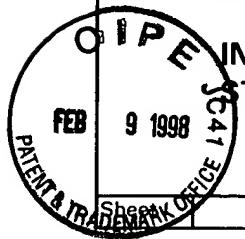
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		Tzartos, et al., Autoimmunity 8:259-270 (1991)	
		van Dam, et al., "Cloned Human snRNP Proteins B and B' Differ Only in Their Carboxy-Terminal Part", EMBO J., 8(12):3853-3860 (1989)	
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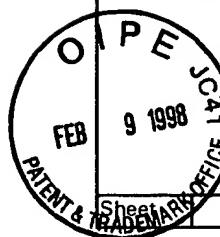
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Sheet 20 of 21

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Application Number	08/781,296
Filing Date	January 13, 1997
First Named Inventor	John B. Harley et al.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	OMRF 161

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
		Watson, et al., "Certain Properties Make Substances Antigenic," in <u>Molecular Biology of the Gene</u> , Fourth Edition, page 836, paragraph 3, (The Benjamin/Cummings Publishing Company, Menlo Park, 1987)	
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		Xie & Snyder, "Two Short Autoepitopes on the Nuclear Dot Antigen Are Similar to Epitopes Encoded by the Epstein-Barr Virus", <u>Proc. Natl. Acad. Sci.</u> , 92:1639-1643 (1995)	
		Yamamoto, K., et al., "Isolation and Characterization of a Complementary DNA Expressing Human U1 Small Nuclear Ribonucleoprotein C Polypeptide," <u>J. Immun.</u> 140:311-317 (1988)	
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